



02.02.04

DAC \$
RECEIVED

FEB 12 2004

TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Beckmann and Cerretti

RECEIVED

Serial No.: 09/904,954

FEB 06 2004

Group Art Unit No.: 1646

Filed: July 12, 2001

OFFICE OF PETITIONS

Examiner: Prema Maria Mertz

For: DNA ENCODING A HEK-LIGAND POLYPEPTIDE (as amended)

Docket No.: 2814-G

PETITION TO WITHDRAW HOLDING OF ABANDONMENT

Mail Stop Abandonment
Attention: Prema Mertz
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of Abandonment dated January 14, 2004, Applicants respectfully states that the Response in question was mailed and timely filed on May 7, 2003. Enclosed are copies of the date stamped postcard, the Express Mail label, the Fee Authorization/Amendment Transmittal Letter and the Amendment thereto. Applicant(s) hereby petition to withdraw holding of abandonment.

Please charge Deposit Account No. 09-0089 in the amount of \$130.00, which would cover the Petition. The Commissioner is hereby authorized to charge any additional fees, which may be required to the Deposit Account No. 09-0089. An original and two copies of this paper are enclosed.

Applicant(s) request(s) favorable action on this petition.

Please send all future correspondence to:

US Patent Operations/ RNM
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

02/06/2004 AHONDAF1 00000034 090089 09904954

01 FC:1460 130.00 DA

Respectfully submitted,

Randolph N. Mohr
Attorney/Agent for Applicant(s)
Registration No.: 45,590
Phone: (805) 447-8949
Date: January 30, 2004

EXPRESS MAIL CERTIFICATE"Express Mail" mail labeling
number:

EV351338904US

Date of Deposit: January 30, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sherry St. Andrew
Printed Name

Signature



UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

FEB 06 2004

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

RECEIVED

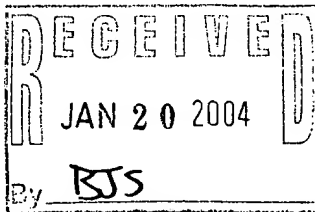
FEB 12 2004

TECH CENTER 1600/2900

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,954	07/12/2001	M. Patricia Beckmann	2814-G	4147

22932 7590 01/14/2004

IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE, WA 98101



EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	14

DATE MAILED: 01/14/2004

COPY



Please find below and/or attached an Office communication concerning this application or proceed:

Patricia Beckmann
3/14/04



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

LR → RNM

RECEIVED

FEB 12 2004

TECH CENTER 1600/2900

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

Docketed: Petition to Revoke

Review: _____

Due Date: 3/14/04

By: LR

EXAMINER

ART UNIT PAPER NUMBER

10

DATE MAILED:

COPY

NOTICE OF ABANDONMENT

This application is abandoned in view of:

☒ Applicant's failure to timely file a proper response to the Office letter mailed on 4/29/03

☐ A response (with a Certificate of Mailing or Transmission of _____) was received on _____, which is after the expiration of the period for response (including a total extension of time of _____ month(s)) which expired on _____.

☐ A proposed response was received on _____, but it does not constitute a proper response to the final rejection.

(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC).

☒ No response has been received.

☐ Applicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date of the Notice of Allowance.

☐ The issue fee (with a Certificate of Mailing or Transmission of _____) was received on _____.

☐ The submitted issue fee of \$ _____ is insufficient. The issue fee required by 37 CFR 1.18 is \$ _____.

☐ The issue fee has not been received.

☐ Applicant's failure to timely file new formal drawings as required in the Notice of Allowability.

☐ Proposed new formal drawings (with a Certificate of Mailing or Transmission of _____) were received on _____.

☐ The proposed new formal drawings filed _____ are not acceptable.

☐ No proposed new formal drawings have been received.

☐ The express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on _____.

☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a) upon the filing of a continuing application.

☐ The decision by the Board of Patent Appeals and Interferences rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

☐ The reason(s) below:

Prema Mertz
**PREMA MERTZ
PRIMARY EXAMINER**



RECEIVED

FEB 06 2004

OFFICE OF PETITIONS

COPY
RECEIVED

FEB 12 2004

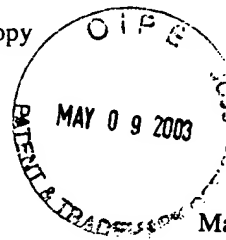
TECH CENTER 1600/2900

THE PATENT OFFICE IS HEREBY REQUESTED TO ACKNOWLEDGE
1 RECEIPT OF THE FOLLOWING DOCUMENTS BY DATE STAMPING AND
1 RETURNING THIS POST CARD

Applicant: Beckmann, et al.
Filed: 07/12/2001
Serial No.: 09/904,954
For: DNA ENCODING A HEK-LIGAND POLYPEPTIDE (as amended herein)
Attorney: Randolph N. Mohr
Enclosures: 1 pg - Amendment Transmittal and 1 copy
7 pgs - Amendment and Response

2814-G
RNM:sd

RECEIVED MAY 30 2003
Express Mail



May 7, 2003

EL360693449US

EL360693449US



UNITED STATES POSTAL SERVICE™



* EL 3 6 0 6 9 3 4 4 9 U S *

POST OFFICE TO ADDRESSEE

ORIGIN (POSTAL USE ONLY)

PO ZIP Code	Day of Delivery	Flat Rate Envelope
Date In	Next	Postage
Mo. Day Year	12 Month	Return Receipt Fee
Time In	Military	
Weight	2nd Day	
lbs. ozs.	3rd Day	
No Delivery on Holiday	Acceptance Clerk Initials	Total Postage & Fees
Weekend		\$ 12.65

CUSTOMER USE ONLY

METHOD OF PAYMENT	WARRANTY OF SIGNATURE (Domestic Only)
Express Mail Corporate Acct. No.	Additional merchandise insurance is void if waiver of signature is requested.
Federal Agency Acct. No. or invoice no.	Signature of addressee or addressee's agent (if delivery employee judges delivery to be made without obtaining signature of addressee or addressee's agent)
Postal Service Acct. No.	NO DELIVERY

FROM: (PLEASE PRINT)	TO: (PLEASE PRINT)
AMGEN INC	Commissioner for Patents
AMGEN CENTER DR	P.O. Box 1450
THOUSAND OAKS, CA 91320-1799	Alexandria, VA 22313-1450
RNM/2814-G	

PRESS HARD.

You are making 3 copies.

FOR PICKUP OR TRACKING CALL 1-800-222-1811

www.usps.gov



PRESS HARD.

You are making 3 copies.

FOR PICKUP OR TRACKING CALL 1-800-222-1811

www.usps.gov



Customer Copy

Mailing Label

826/ 100

F02

RECEIVED
FEB 12 2004
TECH CENTER 1600/2900
RECEIVED
FEB 06 2004
OFFICE OF PETITIONS

PATENT APPLICATION

FEE AUTHORIZATION / AMENDMENT TRANSMITTAL LETTER

Attorney's Docket No: 2814-S

Serial No. 09/904,954	Filing Date 07/12/2001	Examiner Mertz, Prema Maria	Group Art Unit 1646
--------------------------	---------------------------	--------------------------------	------------------------

In Re Application of: M. Patricia Beckmann, et al.

For
DNA ENCODING A HEK-LIGAND POLYPEPTIDE (as amended herein)

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

☐ Applicant(s) request(s) the following extension of time under 37 CFR 1.136(b):

- ☐ One month of original due date (\$110.00)
- ☐ Two months of original due date (\$410.00)
- ☐ Three months of original due date (\$930.00)
- ☐ Four months of original due date (\$1,450.00)
- ☐ Five months of original due date (\$1,970.00)

☒ A response in connection with the matter for which this extension is requested:

- ☒ is filed herewith.
- ☐ has been filed.
- ☐ The response is the filing of a continuing prosecution application, the prior application having an express abandonment conditioned on the granting of a filing date to the continuing application.
- ☒ The accompanying papers include amended claims for which no additional fee is required.
- ☐ The accompanying papers include amended claims the fee for which has been calculated as follows:

CLAIMS AS AMENDED

(1)	(2) Claims remaining After amendment	(3)	(4) Highest number Previously paid for	(5) No. of Extra claims present	(6) Rate	(7) Additional Fee
Total Claims		Minus	=	0	x \$18	= \$ 0.00
Indep. Claims		Minus	=	0	x \$84	= 0.00
<input type="checkbox"/> First Appearance of a multiple dependent claim					+	\$280 = 0.00
Total Additional Fee for this Amendment					\$0.00	

* If the entry in column 2 is less than the entry in column 4, write "0" in column 5.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
 The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col 1. of a prior amendment or the number of claims originally filed.

☐ The following other fees are incurred by the accompanying papers.

☐ Other: _____

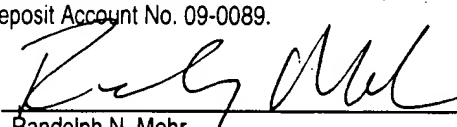
Please charge Deposit Account No. 09-0089 in the name of Immunex Corporation in the amount of \$_____.
 A duplicate copy of this petition is attached.

☒ If an additional extension of time is required, please consider this a request therefore.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required by the accompanying papers, or credit any overpayment to Deposit Account No. 09-0089.

Please Send Future Correspondence To:

Immunex Corporation
 Law Department
 51 University Street
 Seattle, Washington 98101
 (206) 587-0430


 Randolph N. Mohr
 Attorney/Agent for Applicant(s)
 Registration No.: 45,590
 Phone: (805) 447-8949
 Date: May 7, 2003

EXPRESS MAIL CERTIFICATE

"Express Mail" mail labeling number: EL360693449US

Date of Deposit: May 7, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

Lynne Buchsbaum
 Printed Name


 Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

FEB 06 2004

OFFICE OF PETITIONS

RECEIVED

FEB 12 2004

TECH CENTER 1600/2900

Applicants: Beckmann and Cerretti

Serial No.: 09/904,954

Filed: July 12, 2001

For: DNA ENCODING A HEK-LIGAND POLYPEPTIDE (as amended herein)

Docket No.: 2814-G

Group Art Unit No.: 1646

Examiner: Prema Maria Mertz

COPY

Honorable Commissioner for Patents
Washington DC 20231

AMENDMENT

Sir:

In response to the Notice of Non-Compliant Amendment (Voluntary Revised Practice) mailed April 29, 2003 to which a response is due by May 29, 2003, and in response to the Office action of November 18, 2002, please amend the above identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 5 of this paper.

EXPRESS MAIL CERTIFICATE

"Express Mail" mail labeling
number:

EL360693449US

Date of Deposit: May 7, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lynne Buchsbaum

Printed Name

Lynne Buchsbaum
Signature

In the Specification:

Please replace the title with the following rewritten title:

--DNA ENCODING A HEK-LIGAND POLYPEPTIDE --

COPY

COPY

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

Claim 1 (currently amended): An isolated ~~DNA~~ nucleic acid encoding a hek-L protein capable of binding hek, wherein said ~~DNA~~ nucleic acid comprises a nucleotide sequence that is at least 80% identical to a sequence selected from the group consisting of nucleotides 83-796, 83-745, 140-796, and 140-745 of SEQ ID NO:1.

Claim 2 (cancelled).

Claim 3 (currently amended): An isolated ~~DNA~~ nucleic acid encoding a hek-L protein capable of binding hek, wherein said ~~DNA~~ nucleic acid comprises a nucleotide sequence that is at least 80% identical to a sequence selected from the group consisting of nucleotides 28-630, 28-573, 94-630, and 94-573 of SEQ ID NO:3.

Claim 4 (cancelled).

Claim 5 (currently amended): An isolated ~~DNA~~ nucleic acid encoding a human hek-L protein capable of binding hek, wherein said hek-L comprises an amino acid sequence that is at least 80% identical to a sequence selected from the group consisting of amino acids 1-202 and 1-219 of SEQ ID NO:2 and amino acids 1-160 and 1-179 of SEQ ID NO:4.

Claim 6 (cancelled).

Claim 7 (currently amended): An isolated ~~DNA~~ nucleic acid encoding a fusion protein comprising a hek-L polypeptide that binds hek, and an Fc polypeptide, wherein said hek-L comprises an amino acid sequence that is at least 80% identical to a sequence selected from the group consisting of amino acids 1-202 of SEQ ID NO:2 and amino acids 1-160 of SEQ ID NO:4.

Claim 8 (currently amended): An expression vector comprising a ~~DNA~~ nucleic acid according to claim 1.

Claim 9 (currently amended): An expression vector comprising a ~~DNA~~ nucleic acid according to claim 3.

Claim 10 (currently amended): An expression vector comprising a ~~DNA~~ nucleic acid according to claim 5.

Claim 11 (currently amended): An expression vector comprising a ~~DNA~~ nucleic acid according to claim 7.

Claim 12 (original): A process for preparing a hek-L polypeptide, comprising culturing a host cell transformed with a vector according to claim 8 under conditions promoting expression of hek-L, and recovering the hek-L polypeptide from the culture.

Claim 13 (original): A process for preparing a hek-L polypeptide, comprising culturing a host cell transformed with a vector according to claim 9 under conditions promoting expression of hek-L, and recovering the hek-L polypeptide from the culture.

Claim 14 (original): A process for preparing a hek-L polypeptide, comprising culturing a host cell transformed with a vector according to claim 10 under conditions promoting expression of hek-L, and recovering the hek-L polypeptide from the culture.

Claim 15 (previously amended): A process for preparing a hek-L polypeptide, comprising culturing a host cell transformed with a vector according to claim 11 under conditions promoting expression of hek-L, and recovering the hek-L polypeptide from the culture.

Claims 16-27 (cancelled).

Claims 28-39 (withdrawn).

COPY

REMARKS/ARGUMENTS

Claims 1, 3, 5, and 7-15 remain in this application. Claims 28-39 have been withdrawn due to a restriction requirement wherein the Applicants have elected to prosecute Group I (claims 1, 3, 5, and 7-15).

Claims 1, 3, 5, and 7-11 have been amended to more particularly claim that which the inventors consider to be the invention. These amendments are supported throughout the specification and do not represent new matter.

35 U.S.C. 112, First Paragraph (written description)

Claims 1, 3, 5, 7-15 are rejected under 35 U.S.C. 112, first paragraph as allegedly containing subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of the application. In particular, it is alleged that the specification and claims do not indicate what "distinguishing attributes" are shared by the members of the subject matter of the claims, *i.e.*, a nucleic acid genus. And further, it is alleged that there is no common 'structural attributes' given to identify the members of the claimed genus. It is concluded that the disclosure fails to provide a representative number of species to describe the claimed genus and therefore the Applicants were not in possession of the claimed invention.

Applicants' representative traverses this rejection for the following reasons.

In the recent *Enzo* decision (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 01-1230 (Fed Circ., 2002)), the Federal Circuit reviewed with approval the Office's guidelines on written description. In particular, the Court considered claims to antibodies directed to a particular antigen, where no antibodies had been described. In this type of claim there is no structure given in which there is a common structural or distinguishing attribute, as is now required by the present Examiner in order for there to be sufficient written description of the presently claimed invention. However, the Court noted that this type of claim can be sufficient for the purposes of written description when the function of a claimed molecule is sufficient to describe the molecule when the antigen is known. This is particularly true in fields that are developed and mature, such as in antibody/antigen interactions and can be extended to additionally well characterized fields such as ligand/receptor binding which is, like antibody/antigen binding, another example of a protein binding a second protein.

The presently claimed invention encompasses a description of a molecule partly by it's function, *i.e.*, capable of binding its receptor, hek. In addition, the claims also provide additional limitations on the scope of the molecules that can be included in the claimed genus, *i.e.*, at east 80% identity to a known sequence. Thus, the common attributes of the claimed genus are 80% identity to a prescribed sequence, e.g., SEQ ID Nos 1 or 3, and encoding a protein that has the ability to bind hek. This type of claim language, in view of the teachings of the specification, is completely consistent with *Enzo* and therefore, the claimed invention meets the written description requirement.

COPY

It is believed that these two attributes are more than sufficient to meet the written description requirement. It is also noted that claims similar to these are routinely allowed to issue by the Office. However, if the Office finds that these are still insufficient, Applicants' representative request clarification of examples of what would suffice to meet the appropriate standard. Accordingly, in view of the above arguments, applicant respectfully submits that the foregoing rejection is in error and should be withdrawn for the reasons cited.

35 U.S.C. 112, First Paragraph (enablement)

Claims 1, 3, 5, 7-15 are rejected under 35 U.S.C. 112, first paragraph as allegedly not enabling for isolated DNA encoding a hek-L protein that is at least 80% identical to a sequence as set forth in SEQ ID Nos 1 or 3. Further, it is stated that there are no actual or prophetic examples on the expected 'parameters of any of the possible nucleic acid molecules encoding muteins of hek-L' polypeptides.

Applicants' representative traverses this rejection for the following reasons.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, based on the teachings of the specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Teletronics Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). This is so even if the amount of experimentation is laborious. [emphasis added] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Further, the Courts have held that the key word is "undue", not "experimentation." *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976).

In *In re Wands*, the Applicants claimed an assay using any monoclonal antibody that had a high affinity for an antigen. The Applicants used techniques well known in the art to make over 100 monoclonal antibodies. However, it was impossible to predict which of these antibodies would recognize the antigen and which would not without subsequent testing. The Federal Circuit held that even though there was additional testing that would be required to determine the full scope of the claimed invention, it would not constitute undue experimentation. This is analogous to the present situation, where the inventors have set forth a genus of molecules that would need to be tested for their ability to encode a protein capable of binding hek. The type of experimentation required to show a protein interaction, however, is routine as would be recognized by one of skill in the art and is also shown in the examples of the present specification. Therefore, it is respectfully submitted that the amount of experimentation required to enable the claimed invention is not undue.

Indeed, the specification teaches mutant sequences having additions or deletions (pp. 5-7), the regions of the hek-L which are important for ligand-receptor interaction (namely, the extracellular domain, p. 7), and assays for measuring binding of hek-L to its receptor (pp. 11-13 and Example 5 on pp. 29-31).

COPY

- Thus, the amount of teaching provided is more than sufficient to provide enablement to conduct any secondary experimentation. Given the teaching of the specification and the level of skill in the art, the effort required to perform the experiments would be merely routine, and the amount of work needed for determination of the nucleic acids encoding the desired polypeptides would not be undue. Thus, these teachings, considered in light of the above described law are sufficient to enable one of skill in the art to practice the invention without undue experimentation.

The Examiner further objects to the lack of more working examples. However, as long as the specification teaches how to make and use the invention, a particular number or content of illustrative examples are not required. Enablement is met by an objective standard, and therefore one need not teach, and preferably omits, what is well known in the art. *Staehelin v. Secher*, 24 U.S.P.Q.2d 1513, (B.P.A.I. 1992) ("How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance").

Thus, in light of the teachings of how to use the invention, it should not be held that the presently claimed invention is not enabled and withdrawal of this rejection is respectfully requested.

Obviousness-Type Double Patenting

Claims 1, 3, 5, 7-15 are rejected under the judicially created doctrine of obviousness-type double patenting. It is stated that a terminal disclaimer can be filed to overcome statutory double patenting providing the conflicting application and patent are commonly owned. The cited patent, U.S. Patent No. 5,516,658 is indeed commonly owned with the instant application. It is respectfully submitted that a terminal disclaimer will be filed when the Examiner has indicated that the rejections under section 112 are overcome, and the application is in form for allowance.

CONCLUSION

Applicants respectfully submit that the claimed invention of the present application is in proper condition for allowance, and respectfully requests issuance thereto. It is believed that no fee is due with this Amendment, however, if the Office deems that a fee is due then authorization is granted to charge Account Number 09-0089.

Respectfully submitted,



Please Send Future Correspondence To:
Immunex Corporation/RNM
51 University Street Law Department
Seattle, Washington 98101
(206) 587-0430 Date:

Randolph N. Mohr
Attorney/Agent for Applicant(s)
Registration No.: 45,590
Phone: (805) 447-8949
May 7, 2003